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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,328	04/30/2001	George Jackowski	2132.051	3127

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	16

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,328	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 13, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *3-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11 & 14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Search Result 1* .

DETAILED ACTION

1. Applicants' election with traversal of Group I, claims 1 and 2, in Paper No.16, filed February 13, 2003, is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Further, Applicants' request that the Examiner reconsider the requirement to include a similar group of claims as in cited pending application S.N. 09/846,352. It is noted that each pending application is examined based on its own merits. It is acknowledged that it is possible for a rejoinder under *In re Brouwer* and *In re Ochiai*.

3. The requirement is still deemed proper and is therefore made FINAL.

4. Claims 1 and 2 are examined on the merits.

IDS

5. Documents WO 01/05422 and Rohr et al. listed in Paper No. 14, filed December 09, 2002, have not been considered because the instant application does not contain English-language translations to the foreign documents as is required for consideration for a reference. For a document published in a non-English-language, a copy of the translation of the document to the English-language is required. (See MPEP § 609)

Sequence Compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See, for example, Page 27, line 18, and Figures 1 and 2. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because the specification contains amino acid

sequences with sequence lengths that are equal to or greater than 4 amino acid residues and these sequences do not have SEQ ID Nos cited along with each sequence in the specification. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy for the specification, statements under 37 CFR § 1.821(f) and (g), if there is a need to list additional sequences in the listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claim Objections

7. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 is not further limiting from claim 1 due to a lack of disclosure as to what difference in biomarker embodiments are included in claims 1 versus 2.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Specific to claim 1, lines 1-2, the phrase "useful in indicating at least one particular disease state" causes the claim to be vague and indefinite. It is unclear what criteria are being used to indicate occurrence of a particular disease state. Is it indicative of a disease state if a specific marker is present or absent? Clarification of the metes and bounds is required. Claim 2 is rejected due to being directly or indirectly dependent from claim 1.

LACK OF UTILITY UNDER 35 U.S.C. § 101:

11. The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

12. Claims 1 and 2 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

13. The claimed subject matter is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

14. It is acknowledged that Applicants identified a specific marker which is evidentiary of at least one specific disease state, where by the presence of said marker serves as a positive indicator of disease (Pages 25-27 and Figures 1 and 2). Further, Applicants disclose that possession of disease specific marker is useful in the production of methods and devices (radioimmunoassay, enzyme-linked innuosorbent assay, "sandwich assays, precipitin reactions, gel diffusion immunodiffusion assay, agglutination assay, and thereof) useful as point-of-care rapid assay diagnostic or risk assessment devices as are known in the art (Pages 28-31). However, the disclosure is not substantial because the specification lacks a description of negative controls in order to establish the specificity of the claimed biopolymer marker.

15. Applicants disclose serum samples from individuals were processed for profiling analysis (Pages 20-27). The lack of disclosure of whether the said biopolymer marker is only present in individuals inflicted with a specific disease but not in the control population or it is present in higher concentration relative to the control population supports that no substantial utility has been established for the claimed subject matter. As mentioned above, the possession of disease specific marker is useful in the production of methods and devices useful for diagnostic purposes. Without any disclosure for distinguishing individuals inflicted with a specific disease versus individuals not inflicted with the said disease, how does one use the disclosed biopolymer for indicating a specific disease state in individuals?

16. Further, identifying and studying the properties of a protein itself, such as the biopolymer marker represented by SEQ ID NO:1, does not define a "real world" context for use. Similarly, the other listed utilities and asserted utilities as summarized above or in the instant specification is not substantial due to being generic in nature and applicable to many such biopolymer marker.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

19. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

20. Since claims 1 and 2 are not supported by a substantial utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ballance et al. (US PN 5,766883 A).

23. Ballance et al. discloses a composition represented by SEQ ID NO: 14 which is identical to the composition represented by SEQ ID NO:1 of this instant application. It is acknowledged

that SEQ ID NO:14 has a sequence length greater than that of SEQ ID NO:1 of this instant application. Because Applicants do not specify that the critical limitation, biopolymer marker, corresponds to the exact amino acid sequence length of SEQ ID NO:1, SEQ ID NO:14 having a sequence identified as SEQ ID NO:1 meets the critical limitation, therefore, clearly anticipates the claimed invention of claims 1 and 2.

CONCLUSION

24. NO CLAIM IS ALLOWED.

25. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

28. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
3/9/03

ARDIN H. MARSCHEL
PRIMARY EXAMINER